

UNITED STATES DEPARTMENT OF COMMERCH United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------|----------------------|---------------------|------------------|
| 10/733,150 | 12/10/2003 | Chia Soo | 62855.4 | 8266 |
| Zhaoyang Li | 7590 01/25/200 | EXAMINER | | |
| Squire, Sander | s & Dempsey L.L.P. | EPPS FORD, JANET L | | |
| Suite 300 One Maritime Plaza San Francisco, CA 94111 | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| | | | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/25/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/733,150 | SOO, CHIA | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Janet L. Epps-Ford | 1633 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | • | | | | | |
| 1) Responsive to communication(s) filed on 13 No | ovember 2006 | · | | | | |
| | action is non-final. | | | | | |
| | , | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| | | | | | | |
| · · · · · · · · · · · · · · · · · · · | Claim(s) 1-53 is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) <u>1-16 and 28-53</u> is/are withdrawn from consideration. | | | | | |
| | 5) Claim(s) is/are allowed. | | | | | |
| | Claim(s) 17-27 is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner | r. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correcti | on is required if the drawing(s) is ob | ected to. See 37 CFR 1.121(d). | | | | |
| 11) The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of: | priority under 35 U.S.C. § 119(a) |)-(d) or (f). | | | | |
| Certified copies of the priority documents | 1. Certified copies of the priority documents have been received. | | | | | |
| Certified copies of the priority documents | 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau | (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
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| | · | | | | | |
| Attachment(s) | _ | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | |
| 2) ☐ Notice of Dialisperson's Patent Diawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) 5) ☐ Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

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DETAILED ACTION

Election/Restrictions

- 1. Applicant's election of group V, claims 17-27 in the reply filed on 11-13-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Moreover, Applicants further elected fibromodulin as the species for prosecution. According to Applicants claims 17-27 all read upon the elected fibromodulin.
- 2. Claims 1-16 and 28-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11-13-06.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al. (WO 93/09800 A1-see Reference B1 on the IDS filed 7-31-06).

The instant claims are interpreted as being drawn to a composition comprising fibromodulin and a pharmaceutically acceptable carrier, wherein the intended use of the composition is for skin care. The limitation wherein the skin is "non-intact, epidermally

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injured skin," does not add any structural limitation to the claims. Prior art disclosing the components of the claimed compositions will be interpreted as anticipating the instant claims despite the intended use recited in the claims, since there is no evidence that the intended use limitations would result in any structural difference between the claimed invention and the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Ruoslahti et al. discloses compositions for the prevention or reduction of scarring by administration of compositions comprising decorin or a functional equivalent of decorin, to a wound (see page 5, lines 17-26). Functional equivalents of decorin include the following (see page 14, lines 21-28):

Functional equivalents of decorin include modifications of decorin that retain its functional characteristics and molecules that are homologous to decorin, such as biglycan and fibromodulin, for example, 25 that have the similar functional activity of decorin. Modifications can include, for example, the addition of one or more side chains that do not interfere with the functional activity of the decorin core protein.

Fibromodulin is clearly disclosed as useful in the compositions of Ruoslahti et al., wherein said compositions are used for skin care.

Pharmaceutical acceptable carriers of the compositions of Ruoslahti et al. include, for example hyaluronic acid (see page 19, lines 3-5; see also page 47 of this

reference for specific embodiments of compositions comprising functional equivalents of decorin and hyaluronic acid). The pharmaceutical compositions of this reference may further comprise other agents that function to promote would healing known to those skilled in the art, such as biologically active chemicals and polypeptides, including for example, an RGD containing polypeptide attached to a biodegradable polymer (see page 19, lines 10-16, and page 47, last 3 lines).

Page 40 of this reference describes methods for purification of fibromodulin.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruoslahti et al. as applied to claims 17-22 set forth above.
- 7. The discussion of Ruoslahti et al. set forth above is incorporated here. However this reference does not disclose the weight percentage of proteoglycan, hyaluronic acid, and at least one additional skin care active (meaning unclear, interpreted as skin care active agent), as set forth in the instant claims.

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to modify the teachings of Ruoslahti et al. to comprise the various weight percentages of the individual components in the design of the instant invention.

Absent evidence to the contrary, "[W]here the general conditions of a claim are

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disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05 [R-5], which states: "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical."

Additionally, in regards to the "at least one additional skin care active" agent limitation, absent evidence to the contrary, it would have been obvious to add an additional skin care active component to the composition of Ruoslahti et al. since the ordinary skilled artisan would have expected to produce an additional composition with the same properties, namely for use as a skin care composition.

Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 23-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-27 recite the phrase "skin care active," the metes and bounds of this phrase are vague and indefinite. It is unclear what applicant's are intending to claim. It is likely that applicant's intended the claims to recite a "skin care active" ingredient, component, or agent.

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10. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-

272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford, Ph.D.

Primary Examiner

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